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Acculaser, Inc.
Summary of 510(k) Premarket Notification
K020657
Acculaser Pro Low Level Laser Therapy Device

Introduction

According to the requirements of 21 CFR §807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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1) Submitter	**Owner-Operator**
Address:	Acculaser, Inc. 12526 High Bluff Drive, Suite 260 San Diego, CA 92130
Contact Person:	Jackson Streeter, M.D., CEO
Telephone:	858-214-2258
Telefax:	858-314-2355
Email:	jstreeter@acculaserinc.com
Date Prepared:	April 30, 2002

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2) Device Name:

Proprietary name:	Acculaser Pro Low Level Laser Therapy
Common name:	Infrared laser
Classification Name(s) and Regulation(s):	Lamp, Non-Heating, for Adjunctive Use in Pain Therapy (21 CFR §890.550);
Product Code:	NHN

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3) Identification of Predicate Devices to which Substantial Equivalence is claimed	The Acculaser Pro Low Level Laser Therapy (LLLT) device is substantially equivalent to MicroLight Corporation of America's MicroLight 830™ Laser System; 510(k)-cleared by the FDA on February 6, 2002 (K010175).

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4) Device Description

The Acculaser Pro LLLT has a hand-held treatment probe, is non-thermal, and emits infrared energy at 830nm.

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5) Intended Use	The Acculaser Pro LLLT device is indicated for adjunctive use in the temporary relieve of hand and wrist pain associated with Carpal Tunnel Syndrome.

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6) Technological Characteristics and Substantial Equivalence Conclusion

The Acculaser Pro LLLT device has the same indications for use and substantially equivalent technological characteristics as the MicroLight 830™ Laser System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2002

Acculaser, Inc.
c/o Patsy J. Trisler, J.D., RAC
Senior Director, PharmaNet Consulting
PharmaNet, Inc.
815 Connecticut Avenue, N.W.
Suite 610
Washington, DC 20006

Re: K020657
Trade/Device Name: Acculaser Pro Low Level Laser Therapy Device
Regulation Number: 21 CFR 890.5500
Regulation Name: Non-Heating, for Adjunctive Use in Pain Therapy
Regulatory Class: II
Product Code: NHN
Dated: April 30, 2002
Received: April 30, 2002

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020657

Device Name: Acculaser Pro Low Level Laser Therapy Device

Indications For Use:

The Acculaser Pro Low Level Laser Therapy Device is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020657

(Optional Format 3-10-98)